

FEB 09 2009

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 211

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 63-R-0105  
CUSTOMER NUMBER: 843

FORM APPROVED  
OMB NO. 0579-0038

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

Univ Of Tennessee Knoxville Off Lab An Care  
2621 Morgan Circle Dr  
Knoxville, TN 37996

Telephone: (865) -974-7342

2007-2008

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

| A.<br>Animals Covered<br>By The Animal<br>Welfare Regulations | B. Number of animal<br>being bred,<br>conditioned, or<br>held for use in<br>teaching, testing,<br>experiments,<br>research, or<br>surgery but not yet<br>used for such<br>purposes. | C. Number of<br>animals upon<br>which teaching,<br>research,<br>experiments, or<br>tests were<br>conducted<br>involving no pain,<br>distress, or use of<br>pain-relieving<br>drugs. | D. Number of animals upon<br>which experiments,<br>teaching, research,<br>surgery, or tests were<br>conducted involving<br>accompanying pain or<br>distress to the animals an<br>for which appropriate<br>anesthetic, analgesic, or<br>tranquilizing drugs were<br>used. | E. Number of animals upon which teaching, experiments,<br>research, surgery or tests were conducted involving<br>accompanying pain or distress to the animals and for wh<br>the use of appropriate anesthetic, analgesic, or tranquiliz<br>drugs would have adversely affected the procedures, res<br>or interpretation of the teaching, research, experiments,<br>surgery, or tests. (An explanation of the procedures<br>producing pain or distress in these animals and the reas<br>such drugs were not used must be attached to this report | F.<br>TOTAL NUMBER<br>OF ANIMALS<br>(COLUMNS<br>C + D + E) |
|---|---|---|--|---|--|
| 4. Dogs   |   | 34  | 37   | 8   | 79   |
| 5. Cats   | 13  | 19  | 21   |   | 40   |
| 6. Guinea Pigs  |   | 4   |  |   | 4  |
| 7. Hamsters   |   | 6   | 452  |   | 458  |
| 8. Rabbits  |   | 4   | 11   |   | 15   |
| 9. Non-human Primates   |   |   |  |   |  |
| 10. Sheep   |   |   | 8  |   | 8  |
| 11. Pigs  |   |   | 3  |   | 3  |
| 12. Other Farm Animals  |   |   |  |   |  |
| Goats   |   | 12  |  |   | 12   |
| 13. Other Animals   |   |   |  |   |  |
| llama   |   | 14  |  |   | 14   |
| Cattle  |   | 25  |  |   | 25   |
| Horses  |   | 45  | 93   |   | 138  |

### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (6)(7)(C)

DATE SIGNED

11/19/08

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

**CUSTOMER NO.**

FORM APPROVED  
OMB NO. 0579-0038

**CONTINUATION SHEET FOR ANNUAL REPORT  
OF RESEARCH FACILITY**  
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

[illegible]

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report, in addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

Print)

DATE SIGNED

11/9/88

**PART 1 - HEADQUARTERS**

(b)(6), (6)(7)(C)

**Column E Explanation**

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

63-R-105

1. Registration Number: \_\_\_\_\_

2. Number 8 of animals used in this study.

3. Species (common name) Dog of animals used in the study.

4. Explain the procedure producing pain and/or distress.

A momentary ( two seconds) noxious electrical stimulus is administered to determine analgesic efficacy based on physiological response after injection of Buprenorphine. The electrical stimulus is transient in nature and does not produce tissue damage.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

This is a pharmacokinetic and pharmacodynamic study to develop a sustained release Buprenorphine formulation for a single injection for prolonged analgesia in dogs. Preliminary data has been collected in studies involving mice. Formulations need to be established for dogs. Please see references :

4. Yu S, Zhang X, Sun Y, Peng Y, Johnson JR, Mandrell T, Shukla AJ, and Laizure SC. (2006) Pharmacokinetics of buprenorphine after intravenous administration in mouse. JAALAS 45(3); 12-17.
5. Shukla AJ, Qu W, et al. Analgesic effect in mice following a subcutaneous injection of suspensions of buprenorphine in three different vehicles. Poster Presentation, AAPS annual meeting, 2007. Manuscript preparation in progress.
6. Shukla AJ, Qu W, et al. Buprenorphine plasma concentration profiles in mice after subcutaneous injections of three different suspensions of buprenorphine in mice. Poster Presentation, AAPS annual meeting, 2007. Manuscript preparation in progress.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

N/A

Agency \_\_\_\_\_ CFR \_\_\_\_\_